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In re Application of :
ANKER et al :
Serial No.: 09/807,558 :
Filed : 17 July 2001 :
Attorney Docket No.: ICI I02 :

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181 filed on 6 July 2004. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed under 35 USC 371 on 17 July 2001.

On 6 January 2004, the Office mailed a 16-way restriction requirement, of claims 1-31, 35-41, 46 and 47 as follows.

> Groups I-X are drawn to methods of administering to a patient one of ten compounds selected from the group consisting of aldosterone, chymase inhibitor, cathepsin inhibitor, receptor blocker, ganglion blocking agent, opiate, scopolamine, xanthine oxidase inhibitor, erythopoietin, and receptor agonist.
>
> Groups XI-XV are drawn to a method of administering digitalis alkaloid, growth hormone, insulin like growth factor, endothelin antagonist or TNF antagonist.
>
> Group XVI is drawn directed to a method of electrically stimulating a patent's muscles.

On 5 February 2004, applicants elected Group I, claims 1-3, 19, 29-31, 35-36, 38-39 (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

On 3 May 2004, Applicant's election with traverse of the invention of Group 1, (claims 1-3, 19, 29- 31, 35-36, 38-39 (in part), and claim 4), filed on 05 February 2004 was acknowledged.

Claims 1-31, 35-41, 46-47 were pending. Claims 32-34 and 42-45 were cancelled. Claims 1-2, 19, 29-31, 35-36, 38-39, will be searched and examined in so far as they pertain to a method of administering to a patient a compound that inhibits the effect of aldosterone, claims 3 and 4 would be searched and examined in full. Claims 5-18, 20-28, 37, 40-41 and 46-47 were withdrawn from consideration by the Examiner as drawn to non-elected inventions.

Applicants traversal was responded to and the requirement maintained and made FINAL.

Claims 2, 36, 39 and 41 were objected to for reciting non-elected inventions.

Claims 1, 2, 3, 4, 19, 29-31, 35-36, 38-39 and 41 were rejected under 35 U.S.C. 112, first paragraph, for scope of enablement.

Claims 35-36, and 38-39 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

Claims 1, 2, 3, 4, 19, 35, 36, 38, 39 and 41 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1-4, 19, 29-31 and 41 were rejected under 35 U.S.C 102(b) as being anticipated by RALES investigators (October 1996).

Applicants filed responses on 9 November 2004 (with a certificate of mailing date of 4 November 2004) and 10 February 2005.

DISCUSSION

The application, file history and petition have been considered carefully. In the Petition, Applicants requests reconsideration of the lack of unity determination.

Claim 1, a generic linking claim, is reproduced below.

> 1. A method of treating weight loss due to underlying disease in a patient the method comprising administering to the patient an effective amount of an agent which reduces sympathetic nervous system activity and/or improves cardiovascular reflex status.

Applicants elected Group I, claims 1-3, 19, 29-31, 35-36, 38-39 (in part) and claim 4, drawn to a method of administering to a patient a compound that inhibits the effect of aldosterone with traverse.

The petition sets forth the following concerns:

(A) The claims form a single general inventive concept defined by Claim 1.

(B) The Examiner improperly limited the scope of the generic claims.
(C) The claims should have been divided into at most 4 groups
(D) The alternatives are of similar nature under Markush Practice
(E) Division of a single claim into multiple inventions is improper.

Concerning (C), applicants propose the following 4 groups:

> Group I, claims 1-27, 29-31, 35 and 36, drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.
>
> Group II, claims 28, 37, 46 and 47, drawn to a method of treating weight loss by electrically stimulating the patient's muscles.
>
> Group III, claims 38-40, drawn to a method of enhancing exercise performance.
>
> Group IV, claim 41, drawn to a method of treating weight loss associated with a cardiovascular disorder.

Concerning (A), (C) and (D), the arguments that the alternatives are of similar nature and have unity of invention is not persuasive. The products listed in claim 2, for example do not share a common structure essential for the common utility. Moreover, the products used in the methods do not belong to a single art-recognized class of compounds. For example, erythropoietin is recognized as a blood cell growth factor while spirononlactone is recognized as an agent that inhibits the effects of aldosterone.

Moreover, the technical feature shared among the inventions, amethod of administering an agent that decreases sympathetic nervous activity and/or improves cardiovascular reflex status, does not make a contribution over the prior art, as evidenced by Mueller et al. The arguments that Mueller et al does not teach the use of propanolol for the treatment of cachexia is not persuasive as they are not commensurate in scope with the claimed invention, which contains the sole active step of administering an agent to reduce sympathetic nervous system activity and/or improves cardiovascular reflex status. Additional evidence that the technical feature linking the inventions does not make a contribution over the prior art is provided by the art rejections of Claims 1-4, 19, 29-31 and 41 under 35 U.S.C 102(b) as being anticipated by RALES investigators (October 1996) in the Office action mailed 3 May 2004. For these reasons, the lack of unity determination between the Groups is appropriate.

Concerning (E), Applicants argue that division of a single claim into multiple inventions is improper. This is incorrect.

37 CFR 1.475(E) provides for division within a single claim:

> The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Concerning (B), Applicants are correct that the restriction requirement failed to identify and properly treat linking claims. The examiner should have included form paragraph 8.12 in the Office actions which would have informed applicants:

> Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, the examiner erred in limiting the examination of the generic linking claims to the elected invention, a method of administering a compound that inhibits the effect of aldosterone. Applicants are correct that they are entitled to examination of any generic linking claims along with the elected invention.

The objection to claims 2, 36, 39 and 41 as set forth at pp. 5-6 of the Office Action (5/3/2004) for containing non-elected inventions is also improper in view of the generic linking claims. MPEP 809.04 states that

> Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the case claims to the nonelected invention or inventions.
>
> If a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim.

Moreover, the statement made in paragraph 1b, page 2 of the Office action mailed 3 May 2004 is improper. The office cannot limit the search of generic linking claims 1, 29-31, 35 and 38 to the elected method.

DECISION

The petition under 37 CFR 1.144 filed on 04 June 2004 is **GRANTED IN PART** as follows.

The lack of unity determination stands with respect to the individual types of agents as they lack unity of invention.

The petition is persuasive concerning identification and treatment of linking claims. Should any of the generic linking claims 1, 29-31, 35, 38 become allowable, claims which depend upon and include all the limitations of the allowable claims will be considered for rejoinder. Should the rejoined claims be drawn to different inventions, the restriction requirement between the elected invention and the rejoined invention(s) will be withdrawn.

The application will be forwarded to the examiner for consideration of the responses filed 9 November 2004 and 10 February 2005 and preparation of an Office action consistent with this decision.

There is no fee required for the filing of this petition. The petition fee paid of $130.00 has been credited to Applicants' Deposit Account Number 50-3129.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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